

JUL 16 2001

K61/402 (P.10P2)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

1. SUBMITTER INFORMATION

- a. Company Name: SenoRx Inc.
- b. Company Address: 11 Columbia, Suite A
- c. Telephone: (949) 362-4800
Facsimile: (949) 362-3519
- d. Contact Person: Amy Boucly
Director, Regulatory Affairs
and Quality Assurance
- e. Date Summary Prepared: May 3, 2001

2. DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: Biopsy Site Marker
(Trade Name is to be determined.)
- b. Classification Name: Implantable Staple, 21 CFR 878.4750

3. IDENTIFICATION OF PREDICATE DEVICES

- Gel Mark™ Biopsy Site Marker SenoRx Inc.
- MicroMark™ Biopsy Clip Ethicon Endo-Surgery
- Caris™ Site Marker Artemis Medical, Inc.

4. DESCRIPTION OF THE DEVICE

The SenoRx Biopsy Site Marker consists of a disposable applicator containing resorbable pellets. Some pellets contain a wire form, which is intended for long-term marking of the biopsy cavity.

5. STATEMENT OF INTENDED USE

The Biopsy Site Marker is intended to radiographically mark breast tissue during a percutaneous breast biopsy procedure.

6. COMPARISON WITH PREDICATE DEVICES

The intended use, design, construction, marker material and nominal specifications are similar to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 16 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Amy Boucly
Director, Regulatory Affairs
and Quality Assurance
SenoRx, Inc.
11 Columbia, Suite A
Aliso Viejo, California 92656

Re: K011402
Trade/Device Name: Biopsy Site Marker
Regulation Number: 878.4750
Regulatory Class: II
Product Code: FZP
Dated: May 3, 2001
Received: May 7, 2001

Dear Ms. Boucly:

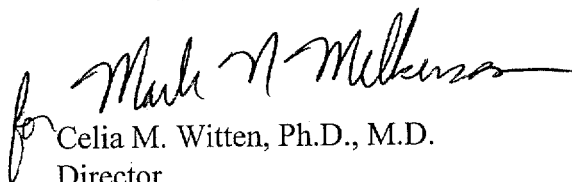
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) number (if known): K011402

Device Name: **Biopsy Site Marker (Trade/Model Name To Be Determined)**

Indications for Use: **The Biopsy Site Marker is indicated for use to radiographically mark breast tissue during a percutaneous breast biopsy procedure.**

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

for Mark A. Milken
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011402